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***APPLICATION NUMBER:***

**75256\_S3**

**APPROVAL LETTER**

ANDA 75-256/S-003

Duramed Pharmaceuticals, Inc.  
Attention: John R. Rapoza  
5040 Lester Road  
Cincinnati, OH 45213

Dear Sir:

This is in reference to your supplemental new drug application dated January 19, 2001, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg.

Reference is also made to your amendment dated October 23, 2001.

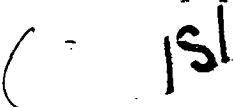
The supplemental application, submitted as "Prior Approval Supplement" provides for

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

 11/13/01  
Rashmikant M. Patel, Ph.D.  
Director  
Division of Chemistry I  
Office of Generic Drugs  
Center for Drug Evaluation and Research